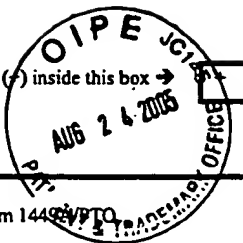


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PTO/SB/08A (08-00)

Substitute for form 1449 PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		<i>Complete if Known</i>	
		Application Number	09/528,682
		Filing Date	March 20, 2000
		First Named Inventor	PIZZA et al.
		Group Art Unit	1631
		Examiner Name	M. Borin
Sheet 1 of 3	Attorney Docket Number	PP000342.0105	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
MTB	A1	5,182,109		Tamura, et al.	01-26-1993

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
MBB	B1	WO	92/19265		AMGEN, INC. AND UNIVERSITY OF SOUTHERN CALIFORNIA	11-12-1992	
	B2	WO	95/09649		MEDEVA HOLDINGS B.V.	04-13-1995	
	B3	WO	95/34323		CONNAUGHT LABORATORIES LIMITED	12-21-1995	
	B4	WO	99/58145		UNIVERSITY OF BRISTOL	11-18-1999	
	B5	WO	00/18434		AMERICAN CYNAMID COMPANY	04-06-2000	
PWS	B6	EP	0396964		SCLAVO S.P.A.	11-14-1990	
	B7	EP	0462534		SCLAVO S.P.A.	12-27-1991	

Examiner Signature		Date Considered	11/09/05
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<sup>1</sup> Unique citation designation number.

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<sup>3</sup> Unique citation designation number.

<sup>4</sup> See attached Kinds of U.S. Patent Documents.

<sup>5</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

<sup>6</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>7</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

<sup>8</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	09/528,682		
		Filing Date	March 20, 2000		
		First Named Inventor	PIZZA et al.		
		Group Art Unit	1631		
Examiner Name	M. Borin				
Sheet	2	of	3	Attorney Docket Number	PP000342.0105 (2300-0342.10)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
<i>MB</i>	C1	Burnette, "The Advent of Recombinant Pertussis Vaccines." <i>Biotechnol.</i> 8:1002-1005 (1990)
	C2	Burnette, <i>Vaccine Research &amp; Developments</i> Chapter 6, Marcel Dekker Inc., New York, New York (1992)
	C3	Communication to EPO Concerning Replacement Claims for Filing with the EPO in Application No. 99922284.7 (2003)
	C4	de Haan, et al., "Mutational Analysis of the Role of ADP-Ribosylation Activity in the Adjuvant Properties of the Escherichia Coli Heat-Labile Enterotoxin Towards Intranasally Administered Keyhole Limpet Hemocyanin." <i>Eur. J. Immunol.</i> 28:1243-1250 (1998)
	C5	Del Guidice, et al., "Genetically Derived Toxoids for use as Vaccines and Adjuvants." <i>Vaccine</i> 17:S44-S52 (1999)
	C6	Dickinson & Clements, "Dissociation of Escherichia coli heat-labile enterotoxin adjuvant activity from ADP-ribosyltransferase activity", <i>Infect. Immunity</i> , 63:1617-1623 (1995)
	C7	EPO Communication pursuant to Article 96(2) EPC relating to Application EP No. 94928455.8-2116 (2001)
	C8	"Multicomponent Vaccine Development." <i>NIH Guide</i> Volume 22, Number 28 (1993)
	C9	Green, Bruce, Curriculum Vitae
	C10	Grant et al., "Role of trypsin-like cleavage at arginine 192 in the enzymatic and cytotoxic activities of Escherichia coli heat-labile enterotoxin", <i>Infect. Immun.</i> , 62:4270-4278 (1994)
	C11	Hagen, Michael, Curriculum Vitae
	C12	Hagiwar, et al., Effectiveness and Safety of Mutant Escherichia Coli Heat-Labile Enterotoxin (LT H44A) as an Adjuvant for Nasal Influenza Vaccine." <i>Vaccine</i> 19:2071-2079 (2001)
	C13	Hartman, et al., "Native and Mutant Forms of Cholera Toxin and Heat-Labile Enterotoxin Effectively Enhance Protective Efficacy of Live Attenuated and Heat-Killed Shigella Vaccines." <i>Infect. Immun.</i> 67:5841-5847 (1999)
	C14	Hazama, et al., "Intranasal Immunization Against Herpes Simplex Virus Infection by using a Recombinant Glycoprotein D Fused with Immunomodulating Proteins, the B Subunit of Escherichia Coli Heat-Labile Enterotoxin and Interleukin-2." <i>Immunology</i> 78:643-649 (1993)
	C15	Hirst, et al., "Cholera Toxin and Related Enterotoxins as Potent Immune Modulators." <i>J. Appl. Microb. Symp. Suppl.</i> 48:26S-34S (1998)
	C16	Hirst, <i>The Comprehensive Sourcebook of Bacterial Protein Toxins</i> , Chapter 6, Academic Press, pgs. 104-130, (1999)
	C17	Lobet et al., "Effect of site-directed mutagenic alterations on ADP-ribosyltransferase activity of the A subunit of Escherichia coli heat-labile enterotoxin", <i>Infect. Immun.</i> 59:2870-2879 (1991)
	C18	Lycke, et al., "Strong Adjuvant Properties of Cholera Toxin on Gut Mucosal Immune Responses to Orally Presented Antigens." <i>Immunol.</i> 56:301-308 (1986)
	C19	Lycke, et al., "The Mechanism of Cholera Toxin Adjuvant Activity." <i>Res. Immunol.</i> 198:504-520 (1997)
	C20	Martindale, <i>Royal Pharmaceutical Society of Britain</i> Pharmaceutical Press, London, England, pgs.1277-1304(1993)
	C21	Rappouli, et al., "Structure and Mucosal Adjuvant Activity of Cholera and Escherichia Coli Heat-Labile Enterotoxins." <i>Immunol. Today</i> 20:493-500 (1999)
	C22	Spangler, "Structure and Function of Cholera Toxin and The Related Escherichia Coli Heat-Labile Enterotoxin." <i>Microbiol. Rev.</i> 56:622-647 (1992)
	C23	Streatfield, et al., "Intermolecular Interactions Between the A and B Subunits of Heat-Labile Enterotoxin from Escherichia Coli Promote Holotoxin Assembly and Stability In Vivo." <i>PNAS USA</i> 89:12140-12144 (1992)
	C24	<i>The Comprehensive Sourcebook of Bacterial Protein Toxins</i> , 2 <sup>nd</sup> Ed., Academic Press, pgs. 696-697
<i>MB</i>	C25	Tsuji, et al., "Relationship Between a Low Toxicity of the Mutant A Subunit of Enterotoxigenic Escherichia Coli Enterotoxin and its Strong Adjuvant Action." <i>Immunology</i> 90:176-182 (1997)

Examiner Signature	<i>MB</i>	Date Considered	11/09/05
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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	09/528,682
				Filing Date	March 20, 2000
				First Named Inventor	PIZZA et al.
				Group Art Unit	1631
				Examiner Name	M. Borin
Sheet	3	of	3	Attorney Docket Number	PP000342. 0105 (2300-0342.10)

[illegible]

Examiner Signature	<i>[Signature]</i>	Date Considered	<i>10/08/05</i>
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